

REMARKS

The present application is directed to a method of detecting anti-tumor autoantibodies in an individual by detecting complexes formed by the binding of autoantibodies in a sample from the individual with tumor marker proteins isolated from a bodily fluid obtained from a body cavity or space in which a tumor is or was present in a cancer patient. Claims 9-10, 13-14, and 19-38 were previously cancelled, and Claims 15-18 were previously withdrawn. Claims 1-8, 11, and 12 are currently under examination. Claims 1, 3-8, and 11-18 are currently amended. Support for the amendments can be found at least on page 10, lines 8-15, and on page 19, lines 21-33, of the specification. New Claims 39-44 are added. No new matter is introduced.

Rejection under 35 U.S.C. §102(b)

In the Final Office Action mailed December 21, 2007, the Examiner maintained the rejection of Claims 1-7 under 35 U.S.C. §102(b) as anticipated by Hanash *et al.* (WO 00/26668, hereinafter “Hanash”). Applicants respectfully that the amendments to the claims overcome the rejection.

Hanash mention the use of isolated S100 proteins for the detection of autoantibodies, but fails to describe the source from **where** these S100 proteins have been isolated.

Claim 1 has been amended to specify that the tumor marker proteins are **prepared from a bodily fluid from a body cavity or space in which a tumor is or was present**. The phrase “or associate with” has been deleted. Applicants discovered that the use of tumor marker proteins prepared in this way have a higher specificity and, therefore, provide superior cancer detection results. One skilled in the art would not have envisaged this source of tumor marker proteins in the absence of hindsight reconstruction.

Claim 1 specifies that the body cavity or space is one in which a tumor is, or was, present in one or more cancer patients. The term “body cavity or space” is described

throughout the present specification, such as on page 8, lines 22-35. The Examiner implied that the term “body cavity or space” could include the circulatory system. Applicants respectfully submit that one skilled in the art would understand from the present specification that the term body cavity or space does **not** include the circulatory system.

The Examiner stated that the claims did not describe how the tumor marker protein was prepared in such a way as to patentably distinguish the method from Hanash. Applicants respectfully submit that Hanash fails to describe **any** collection of bodily fluids from a body cavity or space in which a tumor is or was present. Descriptions for the preparation of tumor marker proteins for use in the claimed method can be found throughout the present specification, such as on page 6, line 35 to page 7, line 19 and page 10, lines 4-19.

Claims 2-7 directly depend from Claim 1 and contain all the limitations thereof.

In light of the foregoing remarks, applicants respectfully submit that Hanash fails to anticipate the claimed method and request withdrawal of the rejection of Claims 1-7 under 35 U.S.C. §102(b).

Double Patenting

The Examiner maintained the provisional rejection of Claims 1-8, 11, and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4, and 8 of copending Application No. 10/417,633 (“the ‘633 application”) in view of Robertson *et al.* (WO 99/58978). As mentioned in the Response filed June 23, 2008, applicants wish to defer the filing of a terminal disclaimer in response to this rejection until allowable subject matter in the ‘633 application has been established.

Rejection under 35 U.S.C. §112, first paragraph

The Examiner newly rejected Claims 1-8, 11 and 12 under 35 U.S.C. §112, first paragraph, for lack of enablement. Applicants respectfully traverse.

The examples of the present application describe the preparation of several tumor marker proteins, such as MUC1, MUC16, and c-myc. Sources of antibodies for purification of numerous other tumor marker proteins are provided on page 38 of the present specification.

In light of the foregoing remarks, applicants respectfully submit that the claims are enabled and request withdrawal of the rejection under 35 U.S.C. §112.

Newly added claims

Applicants have added new Claims 39-44.

New Claim 39 specifies that the tumor marker protein is prepared by collecting bodily fluid from the body cavity or space in which a tumor is or was present from one or more cancer patients and isolating the tumor marker protein from the bodily fluid using protein purification techniques. Support for this new claim can be found in the present specification on, at least, page 6, line 35 to page 7, line 3 and page 9, line 25 to page 10, line 15.

New Claim 40 specifies that the tumor marker protein is prepared by collecting bodily fluid from the body cavity or space in which a tumor is or was present from two or more cancer patients, pooling the fluid and isolating the tumor marker proteins from the pooled fluid using protein purification techniques. Support for this new claim can be found in the present specification on, at least, page 6, line 35 to page 7, line 3 and page 9, line 25 to page 10, line 2.

New Claim 41 specifies that the isolated tumor marker protein is substantially immunoglobulin free. Support for this claim can be found on at least page 11, lines 22-27.

New Claim 42 specifies that the bodily fluid is **not** from the circulatory system, and new Claim 43 specifies that the bodily fluid is **not** whole blood or serum. Support for Claims 41 and 42 can be found in the present specification on, at least, page 8, lines 37-40.

Claim 44 specifies that the bodily fluid is produced during the disease process in response to or as a consequence of the presence of tumor cells. Support for this new claim can be found on, at least, page 8, lines 28-33.

CONCLUSION

The foregoing is submitted as a full and complete response to the rejections in the Final Office Action mailed October 1, 2008. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney is respectfully solicited.

Respectfully submitted,

/Jamie L. Greene/

By: Jamie L. Greene
Reg. No. 32,467

KILPATRICK STOCKTON LLP
1100 Peachtree Street, Suite 2800
Atlanta, GA 30309-4530
Phone: (404) 815-6500
Facsimile: (404) 815-6555
Docket No. 49409-315804 (0041)